IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
ATHENS DIVISION

STEPHEN R. COLLETT and FELICITY COLLETT,	*	
Plaintiffs,	*	
vs.	*	CASE NO. 3:18-CV-66 (CDL)
OLYMPUS MEDICAL SYSTEMS CORP. and OLYMPUS AMERICA INC.,	*	
Defendants.	*	

O R D E R

Stephen Collett claims that he contracted human immunodeficiency virus (HIV) from a colonoscope that was manufactured by Olympus Medical Systems Corp. and Olympus America Inc. (collectively "Olympus"). Stephen's wife Felicity also contracted HIV. Plaintiffs brought claims against Olympus for design defect, failure to warn, and fraudulent and negligent misrepresentation. Olympus moved to exclude four of Plaintiffs' experts, and it seeks summary judgment. As discussed below, the motion to exclude Michael Koehler (ECF No. 130) is granted to the extent set forth below but otherwise denied, the other motions to exclude (ECF Nos. 127, 129, 143) are denied, and the summary judgment motion (ECF No. 131) is granted in part and denied in part. This action will be set down for trial during

the Court's next Athens trial term, which begins on May 30, 2023.

SUMMARY JUDGMENT STANDARD

Summary judgment may be granted only "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In determining whether a *genuine* dispute of *material* fact exists to defeat a motion for summary judgment, the evidence is viewed in the light most favorable to the party opposing summary judgment, drawing all justifiable inferences in the opposing party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). A fact is *material* if it is relevant or necessary to the outcome of the suit. *Id.* at 248. A factual dispute is *genuine* if the evidence would allow a reasonable jury to return a verdict for the nonmoving party. *Id.*

FACTUAL BACKGROUND

Stephen Collett underwent a screening colonoscopy on October 10, 2011 at the Athens Gastroenterology Center. His doctor used an Olympus CF-H180AL colonoscope. Stephen's doctor observed a small polyp during the procedure, and he removed it for a biopsy using a cold snare, which Plaintiffs assert caused a breach in the blood barrier of Stephen's colon. Plaintiffs concede that no direct evidence presently exists that infectious HIV was present on the scope eleven years ago; their contention

that the scope was contaminated with HIV rests upon expert testimony that is based on circumstantial evidence.

About three weeks after the colonoscopy, Stephen began to feel ill, and he experienced "fever and night sweats and then developed a rash on [his] body." S. Collett Dep. 103:8-16, ECF No. 135-3. Stephen went to an urgent care center complaining of night sweats, muscle pain, sore joints, and a skin rash. Stephen also complained of a fever, and Plaintiffs contend that the medical records show that he had lymphadenopathy (swollen lymph nodes).[1] Stephen was diagnosed with sinusitis and a possible allergic reaction to a drug.

Stephen had previously suffered similar symptoms following a May 2010 trip to Mexico, including headache, muscle pain, joint pain, rash, and a low white blood cell count. Plaintiffs' medical expert acknowledges that these May 2010 symptoms could be consistent with an acute HIV infection, and Defendants' medical expert admits that these symptoms could be consistent with Dengue fever. Stephen was not tested for either HIV or Dengue fever at the time. He was tested for Rocky Mountain spotted fever and Lyme disease, and those tests were negative.

[1] There is a discrepancy about which document is the correct second page for the November 6, 2011 visit record, and the parties did not point to evidence to resolve the discrepancy. If a factfinder accepts that Plaintiffs' exhibit (Defs.' Mot. for Summ. J. Ex. O, ECF No. 135-6) contains the correct page 2 for the November 2011 urgent care visit, then that would support a finding of lymphadenopathy.

In June 2013, Stephen was admitted to a hospital for a dry cough, fever, night sweats, and twenty-pound weight loss. The next month, Stephen was diagnosed with HIV and AIDS. Felicity also tested positive for HIV in July 2013. Stephen and Felicity have been monogamous since their marriage in 1983 and they have never taken unprescribed intravenous drugs. And, they had both tested negative for HIV in 2002 as part of the process for immigrating to the United States from South Africa.

Shortly after his diagnosis, Stephen began looking for potential non-sexual causes of his HIV. He initially believed that it was possible he contracted HIV when he was working with blood products to develop a rabies vaccine in a South African veterinary lab. Stephen continued his research and later came to believe that there was a connection between the 2011 colonoscopy and his HIV infection. Plaintiffs brought this action against Olympus, asserting claims for design defect, failure to warn, and fraudulent and negligent misrepresentation.[2]

DISCUSSION

To create a genuine fact dispute on any of their claims, Plaintiffs must rely on expert testimony. Olympus argues that Plaintiffs' experts should be excluded and that Plaintiffs thus cannot establish their claims.

[2] Plaintiffs initially brought other claims, including a manufacturing defect claim, but they are only pursuing the four claims listed in the text. Pls.' Resp. to Defs.' Mot. Summ. J. 19-20, ECF No. 136.

I. The Motions to Exclude Experts

Olympus contends that some opinions of Alan Lipschultz set forth in his amended expert report were not properly disclosed and should be excluded. Olympus also seeks to exclude testimony from David Lewis, Steven Marlowe, and Michael Koehler under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

A. Motion to Exclude Alan Lipschultz (ECF No. 143)

Alan Lipschultz is a professional engineer who opines that Olympus did an inadequate risk management analysis for infection control risks of the model CF-H180AL colonoscope. During his deposition in April 2022, Lipschultz testified that he relied on an International Organization of Standardization ("ISO") standard from 2007 when formulating his opinions in this case. Counsel for Olympus pointed out that when the CF-H180AL launched in 2005, the applicable ISO standard was the 2000 version. Lipschultz stated that he would study the 2000 standard and issue an updated report. As all the parties anticipated, Lipschultz issued an updated report to address the 2000 ISO standard, though Plaintiffs did not serve it on Olympus until August 5, 2022, after the close of discovery. According to Olympus, Lipschultz's updated report included a "new opinion"—that Olympus did not produce documentation that it considered

human factors as part of its risk evaluation. Defs.' Mem. in Supp. Mot. Exclude Lipschultz 2-3, ECF No. 143-1.

Olympus filed a motion to exclude Lipschultz's "new opinion" as untimely under Federal Rule of Civil Procedure 37(c). If a party does not identify a witness "as required by Rule 26(a) or (e), the party is not allowed to use that" witness "unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). Expert disclosures must comply with Federal Rule of Civil Procedure 26(a)(2)(B) by providing a "complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(1). Olympus recognizes that an expert may supplement his report under Rule 26(e), but it contends that Lipschultz should have disclosed the "new opinion" earlier.

Whether Olympus produced documentation that it considered human factors is a fact, not an opinion: either Olympus produced such documentation or it didn't. The *opinion* Lipschultz offers is that successful reprocessing of the CF-180AL colonoscope is highly dependent on human factors that Olympus did not consider. This opinion is hardly a surprise. In his original expert report, Lipschultz opined that Olympus "did not adequately identify all of the potential hazards associated with the CF-H180AL" as required by ISO standard 14971, in part because he saw "no evidence that Olympus gave adequate consideration" to

hazardous situations that "can arise from slips, lapses, and mistakes" by clinical users, including reprocessing staff. Defs.' Mot. Exclude Lipschultz Ex. D, Lipschultz Report 9-10 (Mar. 15, 2022), ECF No. 143-6. During his deposition, Lipschultz elaborated on this opinion, explaining that where it is possible, it is "much better from a human factors standpoint to have a hard engineering fix" to prevent users from having to be aware of a product's warnings and cautions. Lipschultz Dep. 105:7-18, ECF No. 143-3. He also noted that "from a human standpoint," the colonoscope's disinfection "instructions are difficult even for the diligent user to follow." *Id.* at 156:18-21; *accord id.* at 108:1-6 (stating that Olympus's "sole mitigation . . . for preventing cross-contamination is that users will follow the reprocessing guidelines," which Lipschultz noted were "very complex").

It is difficult to see how Olympus is prejudiced by inclusion of the "new opinion" in Lipschultz's amended report. Frankly, the opinion is not new, even though the first report did not use the words "human factors." The amended report simply provides more explanation of Lipschultz's opinion that Olympus failed to comply with ISO standard 14971. Even if it were a new opinion, the Court finds that the failure to disclose is harmless. Plaintiffs did not reference the "new opinion" in their response to Defendants' summary judgment motion, so there

is no need to re-depose Lipschultz and re-brief the summary judgment motion on this ground. And Plaintiffs stated that they would not object if Olympus reopened Lipschultz's deposition on the limited topic of the "new opinion." For these reasons, the Court denies Olympus's motion to exclude Lipschultz's "new opinion" (ECF No. 143) but will permit Olympus to reopen Lipschultz's deposition on this limited topic before trial.

B. The *Daubert* Motions

Olympus's other motions to exclude experts are brought pursuant to Rule 702 and *Daubert*. "A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if" his "scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;" his "testimony is based on sufficient facts or data" and "is the product of reliable principles and methods;" and he "reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702. In evaluating the admissibility of expert testimony, the Court must consider whether "the expert is qualified to testify competently regarding the matters he intends to address," whether his methodology "is sufficiently reliable," and whether his testimony will help the trier of fact "understand the evidence or to determine a fact in issue." *Knepfle v. J-Tech Corp.*, 48

F.4th 1282, 1294 (11th Cir. 2022) (quoting *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 562 (11th Cir. 1998)). The Court's goal is to ensure "that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004) (en banc) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). To allow the testimony to be considered by the jury, the Court must find that "'it is properly grounded, well-reasoned, and not speculative.'" *Id.* (quoting Fed. R. Evid. 702 advisory committee's note to 2000 amendments).

1. Motion to Exclude David Lewis (ECF No. 127)

David Lewis is a PhD microbiologist who previously worked as an infection control scientist at the United States Environmental Protection Agency. He opines that the design of the model CF-H180AL colonoscope, combined with Olympus's recommended disinfectant, makes it possible for infectious material from one patient (including HIV) to become trapped in the endoscope and expelled into another patient. He also opines that instead of sterilizing endoscopes with glutaraldehyde as Olympus recommends for the CF-H180AL colonoscope, it would be safer and more effective to sterilize endoscopes with peracetic acid. Olympus does not seriously dispute that Lewis is

qualified to offer expert testimony on these matters. Olympus does argue that Lewis's methodology is not sufficiently reliable to be admitted in this case.

In reaching his conclusion, Lewis relied on (1) his examination of an exemplar Olympus colonoscope, (2) his own research on pathways for transmission of pathogens via endoscopes, and (3) his review of epidemiological studies, including studies on cross-infection from endoscopies. The Court carefully reviewed Olympus's arguments in support of the motion to exclude Lewis. The central argument is not that Lewis's overall method is flawed but that the *conclusions* Lewis reached are wrong because he misinterpreted several of the epidemiological studies on which he relies and advocates a disinfecting method that has not been required by the Food and Drug Administration, though it is used by Olympus in one of its automatic endoscope reprocessors.

Contrary to Olympus's argument, the studies concluding that digestive endoscopy is not a major risk factor for transmitting the hepatitis-C virus—*if the endoscope was properly disinfected*—do not directly contradict Lewis's opinion that the CF-H180AL colonoscope can trap and transmit a virus *if the complicated instructions for use are not adequately followed*. Furthermore, the disputes about Lewis's interpretation of the epidemiological studies and arguments about the relative weight that can be

attributed to Lewis's own research within the hierarchy of research evidence all go to the weight of the evidence, not its admissibility. Olympus may certainly address these arguments during a thorough and sifting cross-examination. But the Court concludes that Lewis is qualified to give expert testimony in this action and that Olympus's present arguments do not support excluding his testimony. The motion to exclude Lewis (ECF No. 127) is denied.

2. Motion to Exclude Steven Marlowe (ECF No. 129)

Dr. Steven Marlowe is a physician who is board-certified in internal medicine and infectious diseases. He has more than thirty-five years of experience in infectious diseases, HIV care, and clinical research. Marlowe reviewed the available medical records for both Stephen and Felicity, as well as the sworn testimony of Stephen and Felicity. In his expert report, Marlowe said he could "state to a high degree of medical certainty that [Stephen's] signs and symptoms following his colonoscopy procedure on October 10, 2011 were consistent with acute HIV infection related to the [colonoscopy] procedure." Mot. to Exclude Marlowe Ex. A, Marlowe Report 2, ECF No. 134. He further opined that Stephen's symptoms following the October 10, 2011 colonoscopy procedure "were consistent with an exposure to HIV *related to the colonoscopy*." *Id.* (emphasis added).

Olympus moved to exclude Marlowe's testimony on the basis that Marlowe did not adequately rule in the colonoscopy or rule out alternative causes as the cause of Stephen's HIV infection. Olympus also sought summary judgment on specific causation because it contended that Marlowe only opined it was *possible* Stephen contracted HIV from the colonoscopy, not that Stephen more likely than not contracted HIV from the colonoscopy. It was clear to the Court that Marlowe held the opinion that Stephen more likely than not contracted HIV during the October 2011 colonoscopy, but the Court was concerned about the level of certainty with which Marlowe held his opinions.[3] To avoid deciding the case on a semantical misunderstanding, the Court propounded three questions to Marlowe. Marlowe responded that he opined, to a reasonable degree of medical/scientific certainty, that Stephen more likely than not contracted HIV during his October 2011 colonoscopy procedure. Verified Resp.

[3] In Georgia product liability cases, proof of causation generally requires reliable expert testimony which is "based, at the least, on the determination that there was a *reasonable probability* that the [product] caused the injury." *Rodrigues v. Ga.-Pacific Corp.*, 661 S.E.2d 141, 143 (Ga. Ct. App. 2008) (emphasis added) (quoting *Zwiren v. Thompson*, 578 S.E.2d 862, 865 (Ga. 2003)); *accord Maczko v. Emps. Mut. Liab. Ins. Co.*, 157 S.E.2d 44, 46 (Ga. Ct. App. 1967) ("The testimony must show at least a probable cause, as distinguished from a mere possible cause."). A reasonable probability means preponderance of the evidence, which is the standard of proof for medical causation. *Est. of Patterson v. Fulton-DeKalb Hosp. Auth.*, 505 S.E.2d 232, 234 (Ga. Ct. App. 1998). So, a medical expert must provide a "realistic assessment of the likelihood that the alleged negligence [or product] caused" the patient's injury. *Id.* In product liability cases involving medical causation issues, Georgia courts often rely on the causation analyses in medical malpractice cases. *See Rodrigues*, 661 S.E.2d at 143 (relying on *Est. of Patterson*).

1, ECF No. 152-1. Marlowe further responded that he considered and ruled out five potential alternative causes of Stephen's HIV infection. *Id.* at 2-4.

Olympus objects to Marlowe's Verified Response, arguing that it should be disregarded as a sham affidavit. The sham affidavit rule "allows a court to disregard an affidavit as a matter of law when, without explanation, it flatly contradicts his or her own prior deposition testimony for the transparent purpose of creating a genuine issue of fact where none existed previously." *Furcron v. Mail Centers Plus, LLC*, 843 F.3d 1295, 1306 (11th Cir. 2016). But "the rule only operates in a limited manner to exclude unexplained discrepancies and inconsistencies, as opposed to those 'which create an issue of credibility or go to the weight of the evidence.'" *Id.* (quoting *Tippens v. Celotex Corp.*, 805 F.2d 949, 953 (11th Cir. 1986)).

In his expert report, Marlowe stated: "there is a reasonable possibility that [Stephen] contracted HIV during the colonoscopy procedure." Marlowe Report at 2. When asked to explain his "reasonable possibility" opinion during his deposition, Marlowe stated: "It was a possibility by virtue of breaching the mucosal barrier, doing a biopsy, that HIV could have entered into his body related to the colonoscopy procedure." Marlowe Dep. 74:11-16, ECF No. 134-1. Counsel asked Marlowe if he could "quantify the likelihood of that

possibility," and Marlowe responded, "No . . . it's just a very reasonable possibility." *Id.* at 74:17-22. He also admitted that he did not have a quantitative assessment of the likelihood of HIV transmission by endoscopy is, other than to say it is a reasonable possibility. *Id.* at 75:21-76:3. These responses are not inherently inconsistent with Marlowe's overall conclusion that Stephen more likely than not contracted HIV from the colonoscopy. The deposition questions Olympus points to in its brief did not seek answers on this overall conclusion. Rather, they addressed only one part of the causation analysis: whether it was *possible* for Stephen to acquire HIV from the colonoscopy. And Marlowe unequivocally testified that it was.

Another part of Marlowe's causation analysis is whether there was another likely cause for Stephen's HIV infection, aside from the colonoscopy procedure. In his expert report, Marlowe stated that based on his review of the medical records, there was no more likely contact than the colonoscopy that was documented in the medical records. At his deposition, Olympus's counsel asked Marlowe about other recognized causes of HIV infection, including whether Stephen's May 2010 symptoms could have been an acute HIV infection caused by a sexual exposure during a trip to Mexico. Marlowe explained that he ruled out sexual exposure because there was no evidence to support it. *Id.* at 100:12-101:2. Marlowe's Verified Response is consistent

with this deposition testimony: Marlowe explained that he ruled out sexual relations as the cause of Plaintiffs' HIV because Stephen and Felicity both testified under oath that they had not had extramarital sexual contact, Stephen and Felicity had no medical history of other sexually transmitted diseases, and there was no record that Felicity was HIV positive before Stephen's diagnosis.

Marlowe's Verified Response also rules out other recognized alternative causes of an HIV infection and explains why. Olympus argues that this response conflicts with his deposition testimony, but Olympus did not point to any part of Marlowe's deposition where he was specifically asked about another possible cause but responded differently.

Olympus's last-ditch effort to exclude the Verified Response is its claim that it does not understand Marlowe's Verified Response. The Court asked Marlowe whether five possible transmission methods were all the medically recognized possible ways that HIV can be transmitted to an adult (blood transfusion, sexual relations, intravenous drug use, cut/breaking of skin coming in contact with HIV+ body fluids, and contact between broken skin/wounds/mucous membranes and an object or device containing body fluids from a person with HIV). The Court instructed that if Marlowe answered "no," he should explain why. Marlowe answered "no." Verified Resp. at 2. As

his explanation, Marlowe added a sixth recognized possible infection method: organ or tissue transplant.[4] Olympus believes, though, that Marlowe's "no" answer may have meant that the five possible transmission methods listed by the Court are not medically recognized ways to contract HIV—that Marlowe is now denying that HIV can be transmitted by sexual contact or a cut that comes into contact with HIV+ blood or body fluids. This argument is borderline frivolous. If Marlowe's "no" answer meant that, he would have said so in his explanation, and he would not have needed to rule out each alternative cause in response to Question 3.

For all these reasons, the Verified Response is not a sham affidavit that must be disregarded. The Verified Response clarifies that Marlowe holds his overall specific causation opinion to a reasonable degree of medical/scientific certainty, and it details why he ruled out alternative causes of Stephen's HIV infection. Thus, the Verified Response makes it clear that Marlowe's methodology does not suffer from the defects Olympus

[4] Olympus argues that Marlowe should not be allowed to add the sixth recognized method, organ or tissue donation, because it is technically included in "some interaction that breaks the mucosa barrier," and Marlowe did not mention it in his deposition. Defs.' Resp. to Marlowe Verified Resp. 5, ECF No. 155. In the referenced portion of the deposition, counsel asked Marlowe to explain his opinion that it was a reasonable possibility Stephen acquired HIV from the colonoscopy, and Marlowe responded that the colonoscopy included a biopsy, "an invasive procedure," and that it "was a possibility by virtue of breaching the mucosal barrier, doing a biopsy, that HIV could have entered into his body related to the colonoscopy procedure." Marlowe Dep. 74:6-16. Nothing about that exchange sought Marlowe's opinion on the likelihood of HIV transmission via organ or tissue transplant.

says it does, namely a failure to rule in each possible cause of Stephen's HIV infection and then systematically and scientifically rule out specific causes until a final suspected cause remains. That is exactly what Marlowe says he did. Olympus quarrels with Marlowe's differential evaluation *conclusions*, but that does not make Marlowe's testimony inadmissible. Rather, these issues are more appropriately handled on cross-examination. Olympus's motion to exclude Marlowe (ECF No. 129) is denied.

3. Motion to Exclude Michael Koehler (ECF No. 130)

Michael Koehler is Plaintiffs' materials expert. He has a PhD in chemistry, and he has decades of experience in product performance and failure analysis, with a focus on polymers and plastics, coatings, metal alloys, and other materials. Koehler opines that the design of the Olympus CF-H180AL colonoscope incorporated materials that increased the risk of cross-contamination between patients. Olympus does not seriously dispute that Koehler is qualified to offer expert testimony on this issue. Olympus does argue that Koehler's methodology is not sufficiently reliable to be admitted in this case.

Koehler concluded that the type of Teflon used to line the colonoscope's instrument channel can be damaged when instruments are passed through the channel, creating a risk that patient debris can remain in the scratches and avoid cleaning. He

further found that the GORE-TEX used on the outer layer of certain internal channels is porous and could harbor patient debris. Koehler also opines that using polysulfone molded over stainless steel for the distal tip of the colonoscope is problematic because cracking of the polysulfone could inhibit cleaning of the colonoscope.

In reaching these conclusions, Koehler (1) reviewed Olympus's engineering design documents, (2) examined an exemplar CF-H180AL colonoscope, (3) reviewed scientific studies regarding the materials used in the CF-H180AL colonoscope, and (4) relied on his education and experience as a scientist skilled in materials selection for engineered products. Koehler did not do his own testing on an exemplar colonoscope, and Olympus contends that this is a fatal flaw in Koehler's methodology. Koehler, though, reviewed the scientific literature and found published studies that already tested his hypotheses on whether the tubing of the colonoscope could be damaged because of the properties of the Teflon and GORE-TEX, as well as instances of damage to the polysulfone distal tip cover of colonoscopes. He also explained that it is common to conduct a literature review as one method to test a hypothesis, so the Court cannot conclude that this method is unreliable. Olympus's criticisms of Koehler's conclusions based on his literature review go to the weight of his testimony, not its admissibility. Olympus also faults

Koehler for examining an exemplar scope that was fifteen years old (while the scope used on Stephen was only one year old at the time of his colonoscopy). This issue, as well, goes to weight, not admissibility.

Olympus argues that even if Koehler used reliable methodology, his materials opinions would not be helpful to the jury because the opinions do not "fit" Plaintiffs' theory of the case. Expert testimony that does not relate to an issue in the case is not relevant and thus not helpful to the jury. *Daubert*, 509 U.S. at 591. Olympus contends that because Koehler does not focus on the precise type of infection that could remain in the colonoscope (instead, his opinion applies to all types of viruses, including HIV), the Court should throw out his testimony. The Court is not persuaded that this is a "fit" problem. Olympus may cross-examine Koehler on how the research he relies on supports his opinion that HIV could be transmitted by a colonoscope with scratched Teflon, porous GORE-TEX, and cracked polysulfone.

Olympus also contends that Koehler's opinions do not fit the facts about the colonoscope that was used on Stephen. In support of this argument, Olympus emphasizes that the colonoscope used on Stephen passed an inspection within a few months after Stephen's colonoscopy, which Olympus suggests conclusively establishes that the colonoscope had no scratches

in the instrument channel or microcracks on the distal tip. But the evidence Olympus relies on in support of this point does not state that the colonoscope was inspected for these issues, so this argument does not preclude "fit." Koehler Dep. Ex. O, ECF No. 131-9 at 462-66.

Olympus's next argument is that Koehler's opinion on alternative materials is not specific enough to establish a feasible alternative design.[5] On this, the Court agrees. Koehler opines that there are other materials that are less susceptible to the problems he identified, but Plaintiffs admit that Koehler did not provide specific alternative materials in his expert report or during his deposition. Plaintiffs contend that Koehler did not anticipate that he might be asked for specific materials or data to support his contention that different materials could be substituted for those Olympus used, even though that information is available. Discovery was the proper time for Koehler to identify specific materials that could have been incorporated into the colonoscope instead of the materials that Olympus used. Plaintiffs admit that Koehler did not make such a disclosure during or before his deposition, and they did not point to any evidence that Koehler ever disclosed

[5] It is not clear to the Court whether Plaintiffs intended to proceed under such a theory. Plaintiffs do clearly intend to proceed under the theory that it was feasible to reprocess the colonoscope in a different way that would have minimized the risk of cross-contamination.

specific alternative materials opinions to Olympus. Thus, Koehler shall not be permitted to offer an opinion on what alternative materials Olympus could have used in the colonoscope. Accordingly, to the extent that Plaintiffs intended to proceed under a theory that a feasible alternative design for the colonoscope existed using different materials, they may not rely on Koehler's testimony to do it.

In addition to his opinions on the materials used in the CF-H180AL colonoscope, Koehler opines that the reprocessing method recommended by Olympus was not adequate to sterilize the colonoscope. Olympus argues that Koehler is unqualified to offer such an opinion because he is an engineer who does not understand the science of disinfecting medical equipment or know what the correct standards are. Most of Olympus's arguments on this point are based on cherry-picking portions of Koehler's deposition out of context. The Court reviewed the cited testimony (and the surrounding testimony), which establishes that Koehler understands that high-level disinfection is recommended for endoscopes. The present record establishes that Koehler is a chemist who is familiar with the materials used in the CF-H180AL colonoscope and the chemical processes for disinfecting such materials. He is also familiar with the disinfectant chemical that Olympus recommended, the process that was recommended for disinfecting the colonoscope, the

disinfectant chemical he contends would have performed better, and the alternative disinfecting process that he says would have been more effective at reducing the potential for cross-contamination. For these reasons, the Court is satisfied that Koehler is qualified to offer an opinion on the reprocessing method, and the Court declines to exclude Koehler's testimony on this issue.

In summary, for the foregoing reasons, Olympus's motion to exclude Koehler's testimony (ECF No. 130) is granted as to his alternative materials opinions but otherwise denied.

II. The Summary Judgment Motion (ECF No. 131)

Plaintiffs brought claims against Olympus for design defect, failure to warn, fraudulent misrepresentation, and negligent misrepresentation. Olympus seeks summary judgment on all the claims. Olympus's main summary judgment argument is that Plaintiffs cannot establish specific causation because Marlowe only said that there was a possibility that the colonoscopy caused Stephen's HIV infection. But, as discussed above, Marlowe opines to a reasonable degree of medical/scientific certainty that Stephen more likely contracted HIV during the October 2011 colonoscopy procedure. Accordingly, Olympus is not entitled to summary judgment on this ground.

Olympus asserts additional bases for summary judgment: that Plaintiffs' claims are time-barred, that they do not have enough

evidence to create a genuine fact dispute on their design defect and failure-to-warn claims, and that they cannot pursue their misrepresentation claims as independent claims. The Court addresses each issue in turn.

A. The Statute of Limitations

The Court previously concluded that, under Georgia's discovery rule, Plaintiffs' cause of action did not accrue until they discovered "'or with reasonable diligence should have discovered that [they were] injured' and that there was a 'causal connection between the injury and the alleged negligent conduct of the defendant.'" *Collett v. Olympus Optical Co.*, No. 3:18-CV-66 (CDL), 2018 WL 6517442, at *4 (M.D. Ga. Dec. 11, 2018) (quoting *Ballew v. A. H. Robins Co.*, 688 F.2d 1325, 1327 (11th Cir. 1982)). Olympus now contends that even under that standard, Plaintiffs' claims are time-barred because they should have discovered some of Lewis's research before they did and used it to connect the HIV infection to the colonoscopy. The Court finds that genuine fact disputes exist on whether Plaintiffs should have discovered the alleged causal connection before they did. Summary judgment on this ground is denied.

B. The Design Defect Claims

To prove their design defect claims, Plaintiffs must establish that the CF-H180AL colonoscope's design is defective and that the defective design caused Plaintiffs' injuries.

Under Georgia law, a product design is "defective" if the risks inherent in the product's design outweigh "the utility or benefit derived from the product." *Dean v. Toyota Indus. Equip. Mfg.*, Inc., 540 S.E.2d 233, 237 (Ga. Ct. App. 2000).[6] In general, weighing the risk-utility factors is the jury's job. *Id.* "When a jury decides that the risk of harm outweighs the utility of a particular design, it is saying that in choosing the particular design, the manufacturer exposed the consumer to greater risk of danger than it should have." *Id.*[7]

Olympus contends that because Plaintiffs' experts concede that colonoscopies are important despite a risk of cross-contamination, Plaintiffs cannot prove a design defect under the risk-utility test. But the most important factor of the risk-utility test is "whether the design chosen was a reasonable one from among the feasible choices of which the manufacturer was aware or should have been aware." *Banks v. ICI Ams., Inc.*, 450 S.E.2d 671, 674 (Ga. 1994). Here, Plaintiffs' main argument is

[6] In this diversity action, Georgia substantive standards of law apply. *Wilson v. Taser Int'l, Inc.*, 303 F. App'x 708, 715 (11th Cir. 2008) (per curiam).

[7] The risk-utility factors include: "the usefulness of the product; the gravity and severity of the danger posed by the design; the likelihood of that danger; the avoidability of the danger, i.e., the user's knowledge of the product, publicity surrounding the danger, or the efficacy of warnings, as well as common knowledge and the expectation of danger, and the user's ability to avoid danger; the state of the art at the time the product is manufactured; the manufacturer's ability to eliminate the danger without impairing the product's usefulness or making it too expensive; and the feasibility of spreading the loss in the price or by purchasing insurance." *Dean*, 540 S.E.2d at 237.

that the CF-H180AL colonoscope's design, combined with the recommended disinfecting process, was unreasonable because of the risk of cross-contamination that could have been mitigated using a different disinfecting process. The Court finds that there is enough evidence to create genuine fact disputes on the risk-utility factors, so summary judgment is not appropriate on this ground.

Olympus also argues that Plaintiffs cannot establish causation. As discussed above, Plaintiffs' general causation experts opine that the design of the model CF-H180AL colonoscope makes it possible for infectious material from one patient (including HIV) to become trapped in the endoscope and expelled into another patient even if the colonoscope is processed using a disinfectant approved by Olympus.[8] Plaintiffs' specific causation expert opines that Stephen more likely than not contracted HIV from the colonoscopy procedure. The Court thus finds that the present record contains genuine fact disputes on causation. Olympus's arguments to the contrary are on matters that go to the weight of the experts' testimony, not its admissibility. Summary judgment on this issue is denied. And

[8] Olympus points out that Athens Gastroenterology used an automated endoscope reprocessor manufactured by Medivators instead of using an Olympus reprocessor. The record suggests that Olympus validated a processing method on its own reprocessor equipment using a glutaraldehyde-based disinfectant and did not validate a similar method on the Medivators reprocessor. Olympus did not point to evidence that the reprocessing methods were substantially different depending on which manufacturer's reprocessor was used.

because genuine fact disputes exist on whether Olympus was aware of and ignored cross-contamination risks associated with the CF-H180AL colonoscope, Olympus is not entitled to summary judgment on Plaintiffs' claim for punitive damages.

C. The Failure to Warn Claims

In addition to their design defect claims, Plaintiffs assert claims for failure to warn. The manufacturer of a medical device has a duty to warn the patient's doctor of the dangers involved with the product, and the warnings "must be adequate or reasonable under the circumstances." *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003). Olympus summarily argues that its warnings were adequate as a matter of law, but genuine fact disputes exist on whether Olympus was aware of cross-contamination risks associated with the CF-H180AL colonoscope and failed to warn doctors that they needed to take extra precautions during reprocessing to minimize the risks.

Olympus argues that even if its warnings were inadequate, Plaintiffs cannot establish causation because Stephen's doctor still uses the CF-H180AL colonoscope and reprocesses it using glutaraldehyde. This evidence, standing alone, does not mandate summary judgment on the failure to warn claim. The relevant question is whether Stephen's doctor would have continued using CF-H180AL and glutaraldehyde if Olympus had warned him that there was a higher risk of cross-contamination of the CF-H180AL

if it was disinfected with glutaraldehyde instead of peracetic acid, such that he needed to use a different reprocessing method to minimize the risk of cross-contamination. It is undisputed that when Dr. Williams purchased the CF-H180AL colonoscope, he also purchased a Medivators automated endoscope reprocessor to disinfect the scope. Dr. Williams testified that "Olympus and Medivators came and set everything up," and "they talked to each other" and taught Dr. Williams and his staff how to disinfect the colonoscope. Williams Dep. 101:2-5, 102:19-20, ECF No. 135-2. Dr. Williams further testified that his staff followed the procedure they were taught by Olympus and Medivators for reprocessing endoscopes. *Id.* at 103:2-11. Based on this evidence, a reasonable jury could conclude that Dr. Williams would have followed a different warning had one been provided, so there is a genuine fact dispute on causation. Summary judgment on this ground is denied.

D. The Misrepresentation Claims

In addition to their other claims, Plaintiffs assert claims for fraudulent and negligent misrepresentation. Olympus argues that these claims are subsumed into Plaintiffs' failure-to-warn claims. Plaintiffs contend that the misrepresentation claims are not subsumed if they are distinct from the failure-to-warn claims, but Plaintiffs offered no explanation of why their misrepresentation claims are different from their failure-to-

warn claims. Their failure-to-warn claims are based on Olympus's failure to warn of the risks of the CF-H180AL colonoscope and the use of glutaraldehyde to disinfect it—and the implication that the CF-H180AL was safe as long as it was disinfected with glutaraldehyde. Plaintiffs did not point to any separate statements that form the basis of their misrepresentation claims. Accordingly, the Court finds that the misrepresentation claims against Olympus are subsumed into the failure-to-warn claims. Olympus is entitled to summary judgment to the extent that Plaintiffs shall not be permitted to pursue separate misrepresentation claims.

CONCLUSION

For the reasons set forth above, the motion to exclude Michael Koehler (ECF No. 130) is granted to the extent explained above but otherwise denied, the other motions to exclude (ECF Nos. 127, 129, 143) are denied, and the summary judgment motion (ECF No. 131) is granted in part and denied in part.

IT IS SO ORDERED, this 23rd day of February, 2023.

S/Clay D. Land
CLAY D. LAND
U.S. DISTRICT COURT JUDGE
MIDDLE DISTRICT OF GEORGIA